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| 09/808,898 | 03/15/2001 | Bruce Bryan | LUME 48487 | 4894 |

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| EXAMINER | |
|---|---|
| LIU, SAMUEL W | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1653 | |

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/808,898 | BRYAN ET AL. | |
| | Examiner | Art Unit | |
| | Samuel W Liu | 1653 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *25 May 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-77* is/are pending in the application.

4a) Of the above claim(s) *14-21,23-37,51-56 and 59-70* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13,22,38-50,57 and 58* is/are rejected.

7)☒ Claim(s) *1, 3, 6-7, 9, 11, 38, 41, 45 and 57-58* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a)☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3/19/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

*Status of the claims*

Claims 1-77 are pending.

The preliminary amendment filed 25 May 2001, which amends claims 19, 26, 40, 47, 53, 58, 64, 67, 70 and 73-74, and Applicants' requests for extension of time of three months (filed 3 December 2003) and two months (filed 25 May 2001) have been entered.

***Priority***

Acknowledge is made of a claim for domestic priority under 35 U.S.C. 119(e) to a provisional application No. 60189691 filed 15 March 2000.

***Object to Oath***

The oath or declaration of this application is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because the signature for the full name of one of inventors Szczepaniak William appears unsigned.

***Election/Restrictions***

Applicants' election (filed 3 December 2003) of Group I, claims 1-13, 22, 38-50 and 57-58 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Therefore, the pending claims 1-13, 22, 38-50 and 57-58 are under examination to the extent that it is drawn to the elected invention.

***IDS***

Please note that Applicants' submission of IDS filed 19 March 2002 is incomplete since it appears to contain only a part of non-patent literatures and foreign documents cited in PTO 1449 form. Examiner has reviewed all the submitted references. Also, note that all the cited US Patent documents are considered by Examiner, and that those references (foreign documents and non-patent literatures) that have been lined-through are not considered by Examiner as to the merits. The instant application thus fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609.

Applicant is advised that the date of submission of any missing items (references cited in this IDS) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C (1).

***Specification/Claim/ Objections***

The disclosure is objected to because of the following informalities:

(1) In page 5, line 25, "SEQ ID Nos. 23-27" should be changed to "SEQ ID NOs: 23-27", and "SEQ ID No. 33" should be changed to "SEQ ID NO:33". The same type of the changes should be made throughout the specification.

(2) In page 13, line 21, "near 540" should be changed to "near 540 nm".

(3) In page 27, lines 13-14, "EM", "UV', and "IR" should be spelled out in full for the first instance of use; see also page 42, line 22, "SSPE".

(4) In claims 1, 3 and 41, "SEQ ID No." should be changed to "SEQ ID NO:".

(5) In claims 1, 3, 6-7, 9, 11, 38, 41, 45 and 57-58, "sequence of nucleotides" should be

changed to "nucleotide sequence".

Appropriate correction is required.

***Claim Rejections - 35 USC § 112, the second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13, 22, 38-50 and 57-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "fluorescent protein encoded by *Renilla reniformis*"; the recitation is unclear regarding by what biomolecule in *Renilla reniformis* the said protein is encoded. Note that "encoded by *Renilla reniformis"* is an incomplete recitation, and that whole organism, e.g., *Renilla reniformis,* can produce but not direct synthesis of (i.e., encode) said fluorescent protein. The dependent claims are also rejected.

Claim 3, item *b*, recites "a sequence of nucleotide that hybridizes under high stringency to …"; the recitation is ambiguous because hybridization condition is widely varied with different characteristics of nucleotide sequences, e.g., length, GC% and secondary structure if any, and the specification does not define the condition. In the absence of a clear definition of the metes and bounds of this recitation, it is unclear as to which condition(s) is actually applied to said hybridization. It is suggested that applicant amends the claims to recite a particular set of hybridization, such as those exemplified on pages 42-43 of the specification, including wash

conditions to overcome this rejection. See also claim 41. Also, claim 3 recitation "SEQ ID Nos." is awkward; what the "Nos" is?

Claim 10 recites the limitation "the plasmid of claim 8". There is insufficient antecedent basis for this limitation in claim 8 from which claim 10 depends. Also, claim 10 is unclear in the recitation "the nucleic acid encoding the cloning site" because the cloning site only functions (e.g., digestion by restriction enzyme) at DNA level NOT RNA that is encoded by the DNA. Does the recitation refer to the nucleic acid comprising instead of encoding the cloning site? Note that the functional cloning site only can be constructed at DNA level not encoded.

Claim 50 recitation "the cell of claim 46" lacks antecedent basis in claims 46, 3 and 1 from which claim 50 depends.

***Claim Rejections - 35 USC §103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-13, 22, 38-50 and 57-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bryan, B. J. et al. (US Pat. No. 6232107, filed 26 March 1999).

Bryan et al. claim an isolated *Renilla reniformis* polynucletotide (see the patent claims 23-24) comprising a coding sequence encoding a *Renilla reniformis* green flurescent protein (GFP). While the polynucelotuide sequence encoding the GFP protein sequence is not described in Bryan et al. patent, the encoded protein sequence reads on SEQ ID NO: 27 of the current application because the source and GFP are the same in the Bryan et al. patent (see claims 1-3). Thus, the polynucleotide disclsoed by Bryan et al. is obvious over the polynucleotide that encodes SEQ ID NO: 27 of the current application claims 1-3.

Bryan et al. teach that said *Renilla reniformis* polynucletotide is DNA (see the patent claims 22-24 and 29), as applied to the applicantion claim 4.

Bryan et al. teach that said *Renilla reniformis* polynucletotide is RNA (see the patent claims 22-24 and 30), as applied to the applicantion claim 5.

Bryan et al. teach a nucleic acid probe (see the patent claim 37) comprising at least 30 nucleotides wherein the probe encodes peptide sequence of SEQ ID NO:25 that is 100% identical to amino acids 71-109 of SEQ ID NO:27 of the instant application, as applied to the application claims 6-8.

Bryan et al. teach a plasmid comprising above-mentioned *Renilla reniformis* polynucletotide whch is an expression vector comrpising a promoter, and a selectable marker wherein the nucleotide seuence encoding *Renilla reniformis* GFP is operatively linked to said

promoter (see the patent claims 31-32). The expression vector also contains a cloning site (see Example 10). The Bryan et al teaching is applied to the application claims 9-10.

Bryan et al. teach a nucleic acid construct encoding a fusion protein, i.e., the *Renilla reniformis* GFP polypeptide and luciferase (see the patent claim 22), as applied to the application claims 11, 38 and 47.

Since Bryan et al. teach that said construct is a plasmid (see the ptent claims 31-32), the above teaching as to the construct anticiapates the application claims 44-45.

Bryan et al. teach a recombinant host cells comprising the above-mentioned plasimd, and the host is a bacterial cell or a yeast cell (see the patent claims 33-34), as applied to the application claims 12-13 and 49-50.

Bryan et al. teach that the luciferase in the construct acts as a transcriptional reporter (see column 85, lines 33-47), as applied to the application claim 22.

Bryan et al. teach that the luciferase encoded by the nucleic acid construct (see the avove statement) is *Renilla mulleri* luciferase of SEQ ID NO:17 (see the patent claims 22 and 27, and column 104) which is 100% identical to the instant papplication SEQ ID NO:17. The Bryan et al. teaching anticiapates claims 39 and 41 and 48 of the current application.

Bryan et al. teach that the above-mentioned luciferase is a *Gaussia princeps* luciferase (see the patent claims 57-58), as appplied to the application claimn 40.

Bryan et al. teach that the nucleic acid construct is DNA (see the patent claim 29) or RNA (see the patent claim 30), as applied to claim 42 and claim 43, respectively.

Becaause the polycistonic message refers to mRNA carrying information for the synthesis of more than one protein, and because the polynucleotide encoding the fusion protein

in the said construct is a polycistronic mRNA (an inherent property of the said polynucleotide), the above Bryan et al. teaching regards to the nucleic acid construct is applied to claim 46 of the current application.

Bryan et al. teach that, in the construct, the nucleotide sequence encoding the luciferase and GFP are not contiguous (see the patent claim 35), as applied to claim 57 of the current application.

Also, Bryan et al. teach that the said construct further comprises a nucleotide sequence encoding a ligand-binding domain of a protein (see the patent claim 36). The Bryan et al. teaching thus is applied to claim 58 of the current application.

***Claim Rejection -Obviousness Type Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

Claims 1-13, 22, 38-50 and 57-58 are rejected under the judicially created doctrine of the obviousness-type double patenting of the claims 1 and 5 in US Pat. No. 6232107. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Bryan et al. claim an isolated *Renilla reniformis* polynucletotide (see the patent claims 23-24) comprising a coding sequence encoding a *Renilla reniformis* green flurescent protein (GFP). While the polynucelotuide sequence encoding the GFP protein sequence is not described in Bryan et al. patent, the encoded protein sequence reads on SEQ ID NO: 27 of the current application because the source and GFP are the same in the Bryan et al. patent (see claims 1-3). Thus, the polynucleotide disclsoed by Bryan et al. is an obvious over the polynucleotide that encodes SEQ ID NO: 27 of the current application claims 1-3. Thus, claims 22-24 of 6232107 disclose the common subject mater of claims 1-3 of the current application, i.e., an isolated *Renilla reniformis* polynucletotide (see the patent claims 23-24, and the attached search result) comprising coding sequence encoding a *Renilla reniformis* green flurescent protein (GFP).

Since claims 22-24 of 6232107 disclose that the isolated polynucleteotide is a nucleic acid **construct** encoding a fususion protein, i.e., *Renilla reniformis* GFP and luciferase; wherein the luciferase is *Renilla mulleri* luciferase of SEQ ID NO:17, the claims 22-24 is an obvious variation of claims 38 and 47-48.

Claims 22 and 27 of 6232107 teach that the luciferase in the said construct (claim 22) is of protein sequence of SEQ ID NO:17 which is from *Renilla mulleri* (see the patent claim 27 and column 104 where describes SEQ ID NO:17). Thus, claims 22 and 27 are an obvious variation of claims 39 and 41 of the current application.

Since the luciferase in the said construct inherently acts as a reporter (see column 85, lines 33-47), claim 22 covers the subject matter set forth in the application claim 22.

Claims 22-24 also covers the commmon subject matter set forth in the application claim 46, which sets forth the luciferase-GFP fusion protein is encoded by a polycistronic message,

because (i) the polycistonic message refers to mRNA carrying information for the synthesis of more than one protein, and (ii) the polynucleotide encoding the fusion protein in the said construct is a polycistronic mRNA (an inherent property of said polynucleotide).

Claims 29 and 30 of 6232107 set forth said nucleic acid contruct of claim 22 is DNA or RNA, respectively, which is commone subject matter of the applicantion claims 4-5 and 42-43.

Claim 37 of 6232107 sets forth a nucleic acid probe comprising at least 30 nucleotides wherein the probe encods peptide sequence of SEQ ID NO:25 that is 100% identical to amino acids 71-109 of SEQ ID NO:27 of the instant application, which is common subject matter of the application claims 6-8.

Claims 31-32 of 6232107 set forth that the above-mentioned construct is a plasmid which is an expression vector comrpising a promoer, a selectable marker wherein the nucleotide seuence encoding *Renilla reniformis* GFP is operatively linked to said promoter (see the patent claim 32), a cloning site (see Example 10). Thus, claims 31-32 of 6232107 are an obvious variation of claims 9-10 and 44-45.

In addition, claim 32 of 6232107 sets forth that the plasmid encodes a fusion protein of the luciferase and GFP, which is common subject matter of claim 11 of the current application.

Claims 56-58 of 6232107 set forth the luciferase in the said construct (claim 22) wherein the luciferase is a *Gaussia princepes* luciferase, which is commone subject matter of the applicantion claims 39-40.

Claims 33-34 of 6232107 set forth a recombinant host cells comprising the above-mentioned plasimd, and the host is a bacterial cell or a yeast cellor a fungal cell or a plant cell or

an insect cel or an animal cell (see the patent claims 33-34), which is commone subject matter of the applicantion claims 12-13 and 49-50.

Claims 35-36 of 6232107 set forth that the nucleotide sequence encoding the luciferase and GFP are not contiguous (see the patent claim 35), and that the above-mentioned construct further comprises a nucleotide sequence encoding a ligand-binding domain of a protein (see the patent claim 36). Thus, clams 35 and 36 are an obvious variation of the application claim 57 and 58, respectively.

Therefore, the instant application and the US Pat. No. 6232107 claims are not patentably distinct from each other.

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is 571 272-0949. The examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low, can be reached on 571 272-0951. The fax phone number for the organization where this

application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.

SWL

Samuel Wei Liu, Ph.D.

February 12, 2004

Karen Cochrane Carlson PhD

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER